REMARKS

I. Status of the Claims

Claims 1, 3, 4, 6, 20 and 21 are pending and under active consideration. Claims 7-19 and 26-43 are withdrawn from consideration. Claims 2, 5 and 22-25 are cancelled. Claims 1 and 20 are currently amended. The amendments to the claims are fully supported by the application as filed. Entry of the claim amendments is respectfully requested.

II. Claim Rejections

A. Rejections under 35 U.S.C. §112, first paragraph

Claims 1-4, 6, 20 and 21 are rejected under 35 U.S.C. §112, first paragraph as allegedly lacking full enablement. According to the Final Office Action, "the specification, while being enabling for: *a pharmaceutical composition comprising an antibody generated using the sFRP-1 of SEQ ID NO: 2*...does not reasonably provide enablement for pharmaceutical compositions comprising antibodies generated using any portions of sFRP-1." Page 3, lines 2-9. According to the Advisory Action, "[t]he claim language "an antibody generated using *a sFRP-1 of SEQ ID NO:2* as an immunogen" encompasses antibodies using a portion or fragment of sFRP-1... [however], [a]mending the claims to "using *the SFRP-1 of SEQ ID NO:2* as an immunogen" would obviate the rejection." 1st paragraph.

Applicants would like to thank the Examiner for the suggestion to obviate the rejection. Applicants are concerned that the introduction of "*the* SFRP-1" may create antecedent basis issues and have instead amended the claims to remove any ambiguity with respect to fragments of SFRP-1. Accordingly, applicants respectfully submit that the instant rejection has been rendered moot in view of the claim amendments. Withdrawal of the rejection is respectfully requested.

B. Rejections under 35 U.S.C. §102(e)

I. Claims 20 and 21 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,433,155 ("Umansky"). The Office Action asserts that Umansky discloses a pharmaceutical composition comprising an antibody against a polypeptide of the SARP (secreted apoptosis related protein) family that includes murine msarp1, as well as human hsarp1, hsarp2, and hsarp3.

According to the Final Office Action, SARP-2 is also known as sFRP-1 and shares 99.7% similarity to the sFRP protein of SEQ ID NO:2 of the present application and exhibits 100% identity to amino acids 217-231 of SEQ ID NO:2. In view of the amendment clarifying that the claims are not directed to antibodies capable of binding fragments of SEQ ID NO:2, the homology of amino acids 217-231 is irrelevant.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. *See* MPEP § 2131 (8th Ed., Rev. 4, Jan. 2006). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Notwithstanding the fact that Umansky does not expressly teach pharmaceutical compositions comprising antibodies capable of specifically binding SEQ ID NO:2, the Advisory Action asserts that "because of the similarity between SARP-2 of Umansky and the instant sFRP-1 (99.7%) identity, one of ordinary skill in the art would recognize that a substantial population of the antibodies encompassed by the prior art would be identical to the instant antibodies." At 2nd paragraph.

The Office Action assumes what is neither disclosed nor inherent in Umansky. While the Office Action identifies fragments of SARP-2 in Umansky that allegedly have overlapping homologous regions with SEQ ID NO:2, the Office Action fails to establish that those overlapping regions are epitopes for each antigen AND that their presentation in the native state of the protein is identical. Accordingly, while an antibody that binds SARP-2 *might perhaps* also bind the polypeptide of SEQ ID NO: 2, this is not necessarily the case.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing being described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999) (Emphasis added).

Claim 20 unambiguously recites an antibody that is capable of specifically binding to the polypeptide of SEQ ID NO: 2. The claims do NOT recite an antibody that binds to a fragment or homologue of SEQ ID NO: 2 and as such, the claimed antibodies do not necessarily bind to the Umansky's SARP-2.

It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002). To anticipate, the asserted inherent function must necessarily be present in the prior art. *Id.*

Since all of the elements of the instant claims are not necessarily present in Umansky, Applicants respectfully requested withdrawal of the anticipation rejection.

II. Claims 20 and 21 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Rubin et al. (U.S. Patent No. 6,479,255) ("Rubin"). According to the Office Action, "[t]he amino acid sequence of FRP taught by Rubin has 96.5% local similarity to SEQ ID NO: 2 of the instant application." The Office Action concedes that Rubin does not expressly teach pharmaceutical compositions comprising antibodies generated by the sFRP protein of SEQ ID NO:2, as presently claimed. Notwithstanding, the Advisory Action asserts that "because of the similarity between FRP of Rubin and the instant sFRP-1 (96.5%) identity, one of ordinary skill in the art would recognize that a substantial population of the antibodies encompassed by the prior art would be identical to the instant antibodies." At 3rd paragraph.

Applicants respectfully traverse this rejection based on the following. As clarified above, the Office Action assumes what is neither disclosed nor inherent in Rubin. While the Office Action identifies fragments of Rubin that allegedly have overlapping homologous regions with SEQ ID NO:2, the Office Action fails to establish that those overlapping regions are epitopes for each

antigen AND that their presentation in the native state of the protein is identical. Accordingly, while an antibody that binds to a sequence in Rubin *might perhaps* also bind the polypeptide of SEQ ID NO: 2, this is not necessarily the case.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing being described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson,* 169 F.3f 743 (Emphasis added).

Claim 20 unambiguously recites an antibody that is capable of specifically binding to the polypeptide of SEQ ID NO: 2. The claims do NOT recite an antibody that binds to a fragment or homologue of SEQ ID NO: 2 and as such, the claimed antibodies do not necessarily bind to the Rubin's sequences.

It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002). To anticipate, the asserted inherent function must necessarily be present in the prior art. *Id.*

Since all of the elements of the instant claims are not necessarily present in Rubin, Applicants respectfully requested withdrawal of the anticipation rejection.

III. Claims 1, 3-4, 6, 20, 21 and 25 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Rubin *et al.* (US 2003/0175864 A1) ("Rubin II"). The Advisory Action asserts that Rubin II teaches an FRP amino acid sequence having 100% similarity to SEQ ID NO:2 of the instant application, citing the sequence alignment for SEQ ID NO: 3 in Rubin submitted with the Office Action mailed April 15, 2008.

Applicants respectfully traverse this rejection based on the following. The sequence referred to as "SEQ ID NO: 3" in Rubin II first appears in its current form in the filing of Rubin II. In other words, SEQ ID NO: 3 in Rubin II is not supported by the application from which it claims priority to. Accordingly, the earliest date which SEQ ID NO: 3 in Rubin II is entitled to, for the purpose of serving as an allegedly anticipatory reference, is May 3, 2002 (i.e. Rubin II's filing date).

In contrast, the pending claims in the present application are fully entitled to *at least* the priority date of PCT/US00/25035 (of which the instant application is the national phase filing), which is September 13, 2000, because SEQ ID NO:2 of the instant application is disclosed in PCT/US00/25035 (*see, e.g.,* claims 1-29 of PCT/US00/25035). Accordingly, SEQ ID NO:3 in Rubin II is not *prior* art. Withdrawal of the rejection is respectfully requested.

C. Rejections under 35 U.S.C. §103(a)

Claim 2 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Rubin et al. (U. S. Publication 2003/0175864) ("Rubin II") in view of Chan *et al.* (*J. Biol. Chem.*, 1992, 267(35):25202-25207) ("Chan"). This rejection is rendered moot in view of the above-arguments and the cancellation of claim 2.

CONCLUSION

Applicants would like to thank the Examiner for the thorough review of this Application. In view of the above amendments and remarks, it is respectfully requested that the outstanding rejections be reconsidered and that all pending claims be allowed. If there are any issues remaining, which the Examiner believes could be resolved through an interview, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: April 6, 2009

By____/Joel Silver/_____
Joel Silver
Registration No.: 53,866

Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Tel. No. (973) 660-6615
Fax. No. (973) 660-7973